K103223
p 1/5

Summary of Safety and Effectiveness

DEC 2 1 2010

Preparation Date: December 17, 2010

Applicant/Sponsor: Encore Medical (d.b.a. DJO Surgical)
9800 Metric Blvd
Austin, TX 78758

Contact Person: William Garzon
Regulatory Affairs Technician

Device Name: Highly Cross-Linked Vitamin E UHMWPE Tibial Insert

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560), OIY, JWH, MBH

Legally Marketed Devices to Which Substantial Equivalence is Claimed:
Encore Medical L.P. - Highly Cross-Linked Vitamin E UHMWPE Tibial Insert, K091956

Device Description:
Subject of this Traditional 510(k) Premarket Notification is a request for labeling claims for the DJO Surgical 3DKnee HXL VE Tibial Insert. The *in vitro* wear claim will be made for the use of the 3DKnee femoral component coupled with a 3DKnee HXL VE Insert. It is important to note that there are no new total knee components being introduced as a result of this Traditional 510(k) premarket notification.

Indications for Use:
Total joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;
- Treatment of fractures that are unmanageable using other techniques

This device may also be indicated in the salvage of previously failed surgical attempts. This device is intended to be used with the 3DKnee System for cemented or uncemented applications.

Intended Use:
DJO Surgical knee devices are intended for treatment of patients who are candidates for knee arthroplasty per the indications for use. While total knee replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

Comparable Features to Predicate Device(s):

- similar product claims
- have the same indicated use,
- incorporate the same design,
- incorporate the same materials,
- have the same shelf life, and
- packaged and sterilized using the same materials and processes

Claims:

The following is a summary of the claims submitted for clearance:

Claim 1:
DJO Surgical HXL VEK showed no measurable oxidation during accelerated age testing per ASTM-2003

FTIR analysis was performed on samples of HXL VEK tibial inserts at three different time points: non- aged, two weeks aged, and four weeks aged. Accelerated aging was performed per ASTM F2003 (oxygen environment at 5 atmospheres at 70°C for 14 and 28 days). The oxidation index was calculated using the method described in ASTM F2102. All three time points showed no detectable oxidation (oxidation indices < 0.1). Oxidation indices were 0.04±0.02, 0.04±0.00, and 0.03±0.02 respectively. As a comparison, oxidation index for Compression Molded UHMWPE (CM) at two weeks aged is 0.73±0.12.

Izod Impact testing was performed on HXL VEK test specimens per ASTM D256 in both pre and post aged material. Impact testing can indicate the relative brittleness of a material; a consequence of oxidation. Accelerated aging was performed per ASTM F2003 (oxygen environment at 5 atmospheres at 70°C for 14 days). CM was used as a control group for comparative purposes. The average impact resistance for CM before and after accelerated aging was 93.5±7.2 KJ/m^2 and 25.1±7.0 KJ/m^2 respectively while the average impact resistance for HXL VEK before and after accelerated aging was 96.2±12.3 KJ/m^2 and 102.3±13.3 KJ/m^2 respectively.

HXL VEK showed no reduction in impact resistance after accelerated aging whereas CM showed marked degradation in impact resistance after accelerated aging.

CM bar stock is machined into a final part and then inspected, cleaned, packaged with nitrogen flush, and sterilized via gamma irradiation.

HXL VEK is UHMWPE powder that is blended with pure liquid pharmaceutical grade alpha-tocopheral (Vitamin E), compression molded, and machined into bar stock. HXL VEK bar stock is then gamma irradiated to cross link the material. The HXL VEK bar stock is then machined into a final part and then inspected, cleaned, pre-packaged, sterilized via gas plasma, and final packaged.

Bench testing is not necessarily indicative of clinical performance.

Claim 2:
DJO Surgical HXL VEK maintains the mechanical strength of conventional compression molded UHMWPE (CM) during mechanical testing.

Tensile testing was performed per ASTM D638 on CM, Highly Cross-Linked (HXL), and HXL VEK material. All test specimens were accelerated aged per ASTM F2003 (oxygen environment at 5 atmospheres at 70°C for 14 days). Average yield strength for each material was 24.98±0.76 MPa, 21.96±0.63 MPa, and 25.09±0.72 MPa respectively. There was approximately a 12% drop off in yield strength for HXL as compared to CM. However, there was no drop off in yield strength for HXL VEK as compared to CM. Maintaining yield strength is a critical parameter for knee tibial insert performance.

Tibial insert posterior peel-out testing was performed to determine the mechanical integrity of the tibial inserts relative to the metal baseplate. A snap feature is utilized to secure the poly inserts to the metal baseplates. Tibial insert test parts that employ identical snap features were manufactured at nominal conditions for both CM and HXL VEK material. Testing was performed to simulate a worst case peel-out phenomenon in which the thickest tibial insert is forced out of the baseplate by applying a load to the insert in the anterior direction. An acceptance criterion was that the HXL VEK inserts should exhibit at least the same amount of resistance to posterior peel-out force as CM inserts. The average resistance load to posterior peel-out for CM and HXL VEK were 169.67±18.18 lbs and 182.43±2.23 lbs respectively.

CM bar stock is machined into a final part and then inspected, cleaned, packaged with nitrogen flush, and sterilized via gamma irradiation.

HXL bar stock is CM bar stock that is gamma irradiated to cross link the material. The HXL bar stock is then machined into a final part and then inspected, cleaned, pre-packaged, sterilized via gas plasma, and final packaged.

HXL VEK is UHMWPE powder that is blended with pure liquid pharmaceutical grade alpha-tocopheral (Vitamin E), compression molded, and machined into bar stock. HXL VEK bar stock is then gamma irradiated to cross link the material. The HXL VEK bar stock is then machined into a final part and then inspected, cleaned, pre-packaged, sterilized via gas plasma, and final packaged.

Bench testing is not necessarily indicative of clinical performance.

Claim 3:
DJO Surgical HXL VEK maintains mechanical strength after accelerated aging.

Tensile, small punch, and Izod Impact testing were performed on HXL VEK before and after accelerated aging. There was no significant decrease in yield strength, ultimate load, or impact resistance after accelerated aging. Accelerated aging was performed per ASTM F2003 (oxygen environment at 5 atmospheres at 70°C for 14 days). Tensile testing was performed per ASTM D638. The average yield strength for HXL VEK before and after accelerated aging was 26.76±0.96 MPa and 25.09±0.72 MPa respectively. Small punch testing was performed per ASTM F2183. The average ultimate load for HXL VEK before and after accelerated aging was 80.80±4.56 N and 81.31±4.22 N respectively. Izod impact testing was performed per ASTM D256. The average impact resistance for HXL VEK before and after accelerated aging was 96.2±12.3 KJ/m^2 and 102.3±13.3 KJ/m^2 respectively.

HXL VEK is UHMWPE powder that is blended with pure liquid pharmaceutical grade alpha-tocopheral (Vitamin E), compression molded, and machined into bar stock. HXL VEK bar stock is then gamma irradiated to cross link the material. The HXL VEK bar stock is then machined into a final part and then inspected, cleaned, pre-packaged, sterilized via gas plasma, and final packaged.

Bench testing is not necessarily indicative of clinical performance.

Claim 4:
DJO Surgical HXL VEK tibial bearings had an average wear rate that was 57% less than that of a conventional direct compression molded UHMWPE (DCM) bearing of the same geometry in knee simulator wear testing.

Wear testing was performed on the 3D™ Knee system comparing DCM tibial inserts and machined HXL VEK tibial inserts. Each test was performed on a multi-axis, force driven knee simulator (Instron/Stanmore 4-Station Knee Simulator) per ISO 14243-1 for 5 million cycles in a 25% concentration of defined bovine calf serum. Both inserts were articulated against a 3D™ Knee CoCr femoral component of matching size. The HXL VEK inserts were aged for two weeks per ASTM F2003 (oxygen environment at 5 atmospheres at 70°C for 14 days) while the DCM inserts were not aged. Both sets of inserts employed soak controls (loaded and unloaded) to correct for fluid absorption of the polyethylene during wear testing. The test specimens were Size 6 Left Femoral Components, Size 6 Left 11mm Inserts, and Size 6 Left Tibial Baseplates. The average wear rate for the DCM and HXL VEK tibial inserts were 4.4±3.0

mg/million cycles and 1.9±1.9 mg/million cycles respectively which was statistically significant ($\rho<0.01$). Even though the HXL VEK inserts were machined and aged (vs. not aged for the DCM inserts), the HXL VEK inserts still showed superior wear properties over the DCM inserts.

Note, reduction in total polyethylene wear volume or wear rate alone may not result in an improved clinical outcome as wear particle size and morphology are also critical factors in the evaluation of the potential for wear mediated osteolysis and associated aseptic implant loosening. Particle size and morphology were not evaluated as part of this wear claim.

DCM parts are inspected, cleaned, packaged with nitrogen flush, and sterilized via gamma irradiation.

HXL VEK is UHMWPE powder that is blended with pure liquid pharmaceutical grade alpha-tocopheral (Vitamin E), compression molded, and machined into bar stock. HXL VEK bar stock is then gamma irradiated to cross link the material. The HXL VEK bar stock is then machined into a final part and then inspected, cleaned, pre-packaged, sterilized via gas plasma, and final packaged.

Bench testing is not necessarily indicative of clinical performance.

Claim 5:
DJO Surgical HXL VEK material was classified as a non-irritant as compared to the control under the conditions of the muscle implantation study.

Intramuscular implant testing was performed per ISO 10993 on three healthy adult New Zealand White rabbits. Compression molded UHMWPE (CM) material was used as the control article to compare to HXL VEK. Five HXL VEK sites and five CM sites were implanted for each rabbit. The surgical sites were closed, and the animals were observed daily for 13 weeks. After 13 weeks, the rabbits were euthanized and the HXL VEK and CM specimens were explanted at necropsy. All tissues were fixed in 10% neutral buffered formalin. Hematoxylin and eosin (H&E) stained sections of the test and control implant sites were prepared from all animals. A veterinary pathologist microscopically evaluated the H&E stained tissue sections of each implant site. There were no gross abnormalities. The average irritant scores for CM and HXL VEK were 5.7 and 5.1 respectively. The Irritant Ranking Score is defined as: Test Group Average – Control Group Average. In this case, 5.1 – 5.7 = -0.6. According to the interpretation of the Irritant Ranking Score, a non-irritant is classified as having a range of 0.0 – 2.9. Therefore, with an Irritant Ranking Score of -0.6, HXL VEK is classified as a non-irritant. Note, inflammatory response to device wear particles has not been evaluated.

CM bar stock is machined into a final part and then inspected, cleaned, packaged with nitrogen flush, and sterilized via gamma irradiation.

HXL VEK is UHMWPE powder that is blended with pure liquid pharmaceutical grade alpha-tocopheral (Vitamin E), compression molded, and machined into bar stock. HXL VEK bar stock is then gamma irradiated to cross link the material. The HXL VEK bar stock is then machined into a final part and then inspected, cleaned, pre-packaged, sterilized via gas plasma, and final packaged.

Per the ISO 10993-1 standard, all permanently implanted medical devices should be evaluated for irritation potential as part of the biocompatibility assessment.

Animal testing is not necessarily indicative of clinical performance.

Non-Clinical Testing:

The following non-clinical laboratory testing was performed to determine substantial equivalence: mechanical material characterization (Tensile, Small Punch, Izod Impact, and crack propagation), physical and chemical characterization (Oxidation Index, Compressive Modulus, Poisson's Ratio, Surface Roughness, Density, Onset Melting Temperature, Peak Melting Temperature, Delta H, Degree of Crystallinity, Crosslink Density, Swell Ratio, Molecular Weight, Polydispersity Index,

Lamallae Thickness, Free Radical Concentration, Vitamin E Concentration, Vitamin E Consolidation, Vitamin E Elution/Extraction, Trans-vinylene Index), tibial insert peel-out strength, wear testing, and biocompatibility. All testing has demonstrated the device is substantially equivalent to the predicate devices.

Clinical Testing:
None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Encore Medical, L.P.
% Mr. William Garzon
Regulatory Affairs Technician
9800 Metric Boulevard
Austin, Texas 78758

DEC 2 1 2010

Re: K103223
Trade/Device Name: Highly Cross-Linked Vitamin E UHMWPE Tibial Insert
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: OIY, JWH, MBH
Dated: October 29, 2010
Received: November 4. 2010

Dear Mr. Garzon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEC 2 1

510(k) Number (if known): K103223

Device Name: Highly Cross-Linked Vitamin E UHMWPE Tibial Insert DEC 2 1 2010

Indications for Use:

Joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;
- Treatment of fractures that are unmanageable using other techniques

This device may also be indicated in the salvage of previously failed surgical attempts. This device is intended to be used with the 3DKnee System for cemented or uncemented applications.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103223